

OBJECTIVES

Ceiling effects limit the discriminative ability of measures in detecting clinically relevant change. While high levels of satisfaction with current treatment are common across many conditions, the resulting ‘skewed’ data are not a failure of the scale but rather reflect a real phenomenon.¹ The HIV Treatment Satisfaction Questionnaire: change version (HIVTSQc) is a condition-specific measure designed to overcome ceiling effects found with the status version (HIVTSQs) of the questionnaire. Both HIVTSQs and c include the same 12 item stems (e.g. items concerning side effects, demands: [Figure 1](#)). However, HIVTSQc response options measure relative change in satisfaction rather than absolute satisfaction. Building on previous work using a treatment satisfaction measure for diabetes,² here we compare the HIVTSQs and c for their ability to demonstrate change.

METHODS

Study details: Latte-2 was a phase IIb study in which treatment-naïve subjects with HIV-1 infection were initially treated with daily oral cabotegravir 30mg + abacavir/lamivudine (ABC/3TC) for 20 weeks (induction period) and then, if virologically suppressed, were randomized to switch to either a long-acting (LA) injectable regimen of cabotegravir LA + rilpivirine LA administered every 4 or 8 weeks or to remain on their daily oral regimen (maintenance phase).

Measures: The HIVTSQs is a 12-item measure of *absolute* satisfaction.³ All items are rated: 6 (very satisfied, convenient, flexible etc.) to 0 (very dissatisfied, inconvenient, inflexible etc.). Items 1–11 are summed to produce a Treatment Satisfaction score (range: 0 to 66). Psychometric analyses³ revealed the discomfort/pain item detracted from the model (multicollinearity with Item 3: side-effects) and is therefore included as a stand-alone item only.

The HIVTSQc is a 12-item measure of *relative* satisfaction. All items are rated: +3 ('much more satisfied now', 'much more convenient now', etc.) to –3 ('much less satisfied now', 'much less convenient now' etc.). Items 1–11 (excluding discomfort/pain) can be summed to produce a Treatment Satisfaction (change) score. Scores range from 33 (improvement in satisfaction) to -33 (deterioration in satisfaction). A score of 0 represents no change. The HIVTSQs can be used without the HIVTSQc. However, the HIVTSQc is designed to be used alongside the HIVTSQs. This is because while the HIVTSQc will tell you how people’s satisfaction has changed it does **NOT** tell you whether treatment satisfaction was high or low to start with, or where it is at endpoint.

Participants completed the HIVTSQs during induction period at Week -16, at Day 1, again during the maintenance phase and at weeks 4, 8 and endpoint (Week 32). The HIVTSQc was completed at Week 32 only.

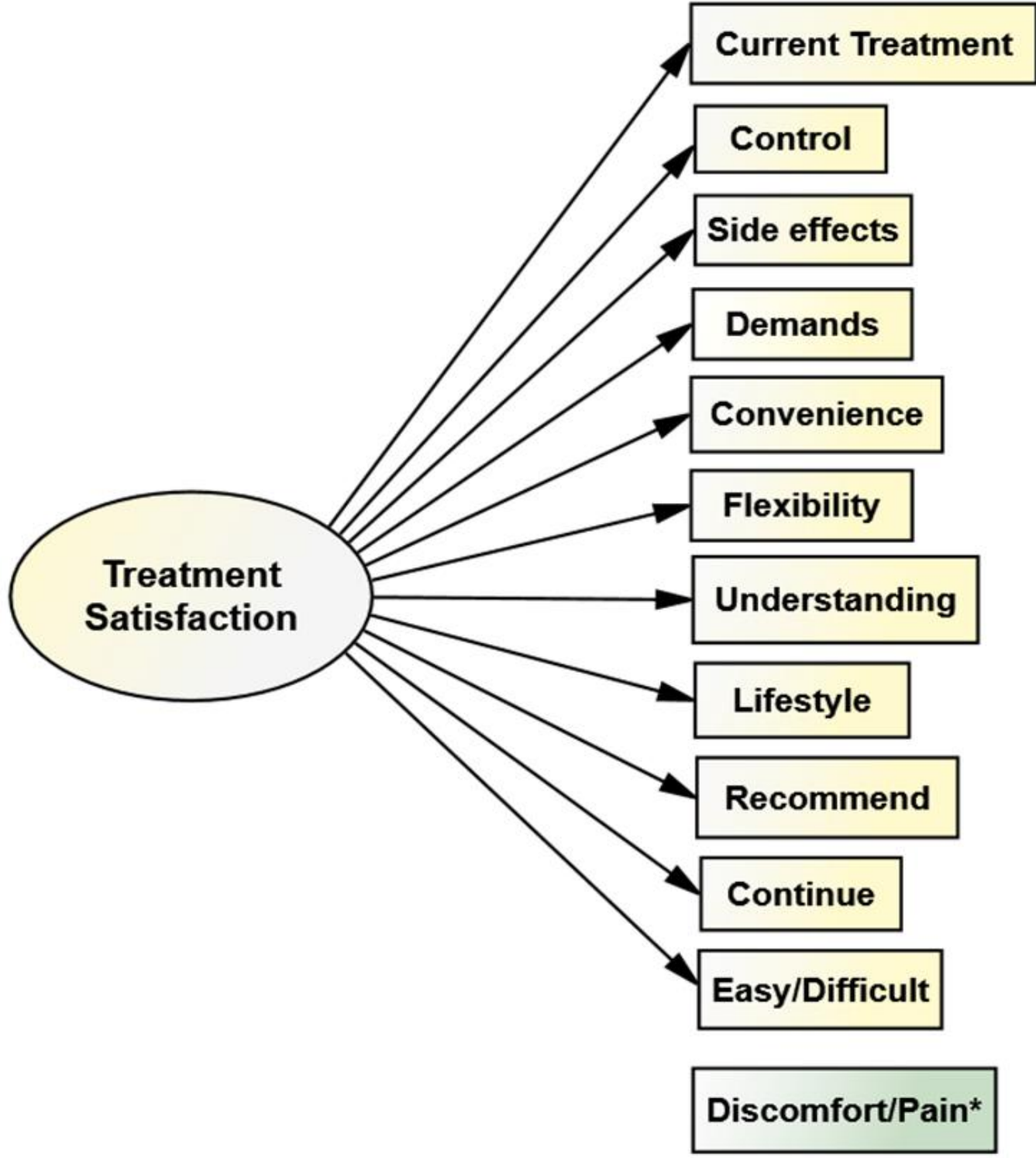


Figure 1: Model of treatment aspects and factor structure of the HIVTSQ
*Item not included in total scale score

Analytic Approach: A 3 x 2 mixed ANOVA was performed:

- **Questionnaire** (HIVTSQc/ HIVTSQs difference (HIVTSQsDiff: HIVTSQs baseline scores minus endpoint scores /2).
- **Treatment** (Tablet/Injection)
- **Ceiling** (Not at Ceiling (Not AC)/At ceiling (AC): using a cutoff score of 53 (66-13 uppermost improvement score).

RESULTS

Participants: Analyses included 250 patients: 47 in the tablet control group and 199 in the injection groups (four missing). At baseline 203 patients were categorized AC (Mean age 38.60 [SD=10.48], men n=187, women n=16) and 47 categorized Not AC (Mean age 33.46 [SD =7.82], men n=41, women n=5).

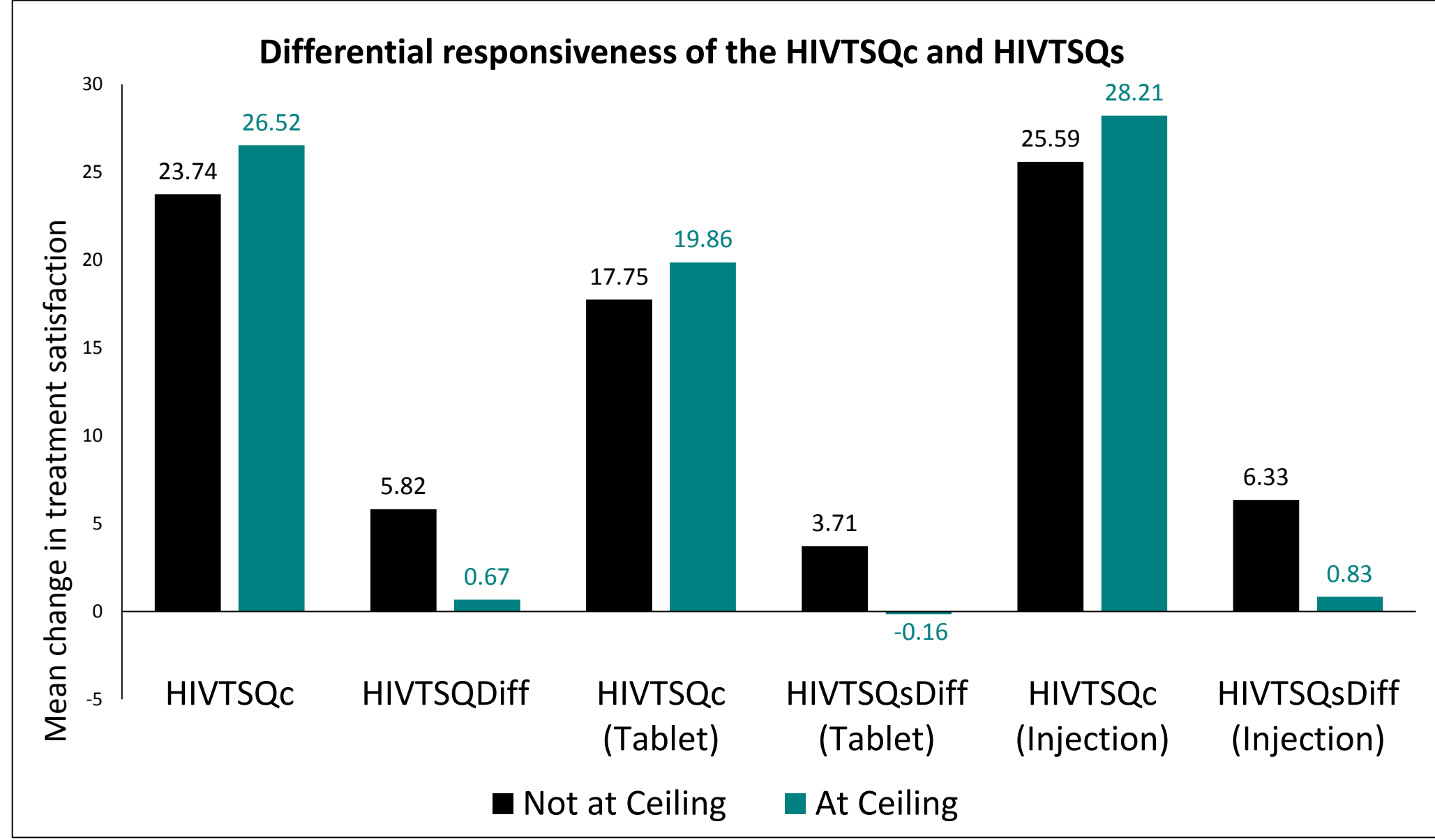


Figure 2: Treatment satisfaction mean scores by questionnaire and ceiling group

The three-way mixed ANOVA revealed significant main effects for Treatment ($F(1,240) = 26.15, p < 0.001$) and Questionnaire ($F(1,240) = 677.38, p < 0.001$) and significant interaction effects for Treatment by Questionnaire ($F(1,240) = 16.44, p < 0.001$) and Questionnaire by Ceiling ($F(1,240) = 20.68, p < 0.001$).

ENQUIRIES & ACKNOWLEDGEMENTS

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Access to the HIVTSQ and other questionnaires developed by Clare Bradley and colleagues can be found at www.healthpsychologyresearch.com
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RESULTS

Tests of simple effects: Questionnaire by Ceiling: Tests of simple effects ([Table 1](#)) for the interaction between Questionnaire by Ceiling revealed that, in both the AC group and Not AC group, treatment satisfaction change scores were significantly higher (showing greater improvement in satisfaction) using the HIVTSQc than when using the HIVTSQsDiff. Differences between the AC and Not AC groups were also found, however only for scores on the HIVTSQsDiff, with significantly greater change in treatment satisfaction found for those in the Not AC group, compared to those in the AC group.

Table 1: Simple effects t-tests for Questionnaire by Ceiling interaction

Questionnaire x Ceiling					
Variable		N	Mean	Standard Deviation	t-test
Not at Ceiling	HIVTSQsDiff	47	5.82	4.66	$t(46), = 14.07, p < 0.001$
	HIVTSQc	47	23.74	8.87	
At Ceiling	HIVTSQsDiff	203	0.67	2.60	$t(202), = 42.88, p < 0.001$
	HIVTSQc	203	26.52	9.38	
HIVTSQsDiff	Not at Ceiling	47	5.82	4.66	$t(52.79), = 7.32, p < 0.001$
	At Ceiling	203	0.67	2.60	
HIVTSQc	Not at Ceiling	47	23.74	8.87	$t(248), = -1.84, p = 0.066$
	At Ceiling	203	26.52	9.38	

Tests of simple effects: Questionnaire by Treatment: Tests of simple effects for the Questionnaire by Treatment type interaction ([Table 2](#)) revealed that while treatment satisfaction change scores were higher on the HIVTSQc than on the HIVTSQsDiff in both the injection group and the tablet group, differences between the injection group and the tablet group scores were only significantly different (higher in the injection group) when using the HIVTSQc. No significant difference was found between the injection group and the tablet group when measured using the HIVTSQsDiff.

Table 2: Simple effects t-tests for Questionnaire by Treatment interaction

Questionnaire x Treatment Type					
Variable		N	Mean	Standard Deviation	t-test
Tablet	HIVTSQsDiff	47	0.83	3.02	$t(46), = 9.69, p < 0.001$
	HIVTSQc	47	19.32	12.89	
Injection	HIVTSQsDiff	197	1.78	3.74	$t(196), = 51.16, p < 0.001$
	HIVTSQc	197	27.76	7.31	
HIVTSQsDiff	Tablet	47	0.83	3.02	$t(242), = -1.63, p = 0.105$
	Injection	197	1.78	3.74	
HIVTSQc	Tablet	47	19.32	12.89	$t(53.25) = -4.33, p < 0.001$
	Injection	199	27.80	7.28	

Effect Size Analyses: As demonstrated in [Table 3](#), for participants in both the AC and Not AC groups (regardless of treatment group), the effect size (r) is stronger for the HIVTSQc compared to the HIVTSQsDiff, indicating that the HIVTSQc is more responsive to change than the HIVTSQsDiff. Furthermore, comparison of these effect sizes revealed a Z score of 10.26 for the AC group and 2.38 for the Not AC group, demonstrating that the HIVTSQc is significantly more responsive for those in the AC group compared to those in the Not AC group.

This pattern of results is also demonstrated in the comparisons of effect sizes amongst the tablet group only (AC HIVTSQc $r=0.59$, HIVTSQsDiff $r=0.03, z=2.59, p=0.009$: Not AC HIVTSQc $r=0.62$, HIVTSQsDiff $r=0.58, z=0.13, p=0.896$) and the injection group only (AC HIVTSQc $r=0.88$, HIVTSQsDiff $r=0.16, z=10.86, p=0.001$: Not AC HIVTSQc $r=0.88$, HIVTSQsDiff $r=0.54, z=3.04, p=0.002$) with the effects being noticeably more marked in the injection group.

Table 3: Comparison of effect size for differences between responses using the HIVTSQsDiff and responses using the HIVTSQc

Variable	N	Mean	Standard Deviation	One Sample t-tests	r	z	p
At Ceiling	HIVTSQc	203	26.52	9.38 $t(202), = 40.28, p < 0.001$	0.82	10.26	<0.001
	HIVTSQsDiff	203	0.67	2.60 $t(202), = 3.66, p < 0.001$	0.13		
Not at Ceiling	HIVTSQc	47	23.74	8.87 $t(46), = 18.35, p < 0.001$	0.80	2.38	0.017
	HIVTSQsDiff	47	5.82	4.66 $t(46), = 8.56, p < 0.001$	0.53		

CONCLUSIONS

Replicating the findings of Bradley et al (2007)² using the Diabetes Treatment Satisfaction Questionnaire status and change versions, the current analyses highlight the limitations of using a status difference measure of change alone in situations where patients may be satisfied with their previous treatment, leaving them little or no room to register improvements in satisfaction with any subsequent treatment. While high levels of satisfaction with current treatment are common across many conditions the resulting ‘skewed’ data are not a failure of the scale but rather reflect a real phenomenon. The results presented here add strong support for the use of the HIVTSQc alongside the HIVTSQs at one time point. As a measure of change in treatment satisfaction the HIVTSQc demonstrated superior responsiveness to change regardless of treatment and treatment type in not only those at ceiling but also those not at ceiling. The HIVTSQc has demonstrated the ability to overcome ceiling effects and in doing so provides greater validity in ensuring that benefits of a new treatment are not overlooked.

REFERENCES

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3. Romaine, J. Murray, M. & Bradley, C. (2016). Psychometric evaluation of the revised HIV Treatment Satisfaction Questionnaire (HIVTSQ). *Value in Health*, 19(7) A420 Abstract PIN76 DOI: 10.1016/j.jval.2016.09.426